K121387

JUN - 5 2012

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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	May 04, 2012
Submitter:	GE Healthcare 540 West Northwest Highway Barrington, IL 60010
Primary Contact Person:	John Manarik Regulatory Affairs Manager GE Healthcare Phone: 847-277-5504 Fax: 847-277-5240
Secondary Contact Person:	Jeme Wallace Regulatory Affairs Director GE Healthcare Phone: 847-277-4468 Fax: 847-939-1446
Device Trade Name:	Centricity* PACS-IW
Common/Usual Name:	Picture Archiving and Communication System
Classification Names:	21 CFR 892.2050, System, Image Processing, Radiological
Product Code:	LLZ
Predicate Device:	K082318 - GE Healthcare Centricity PACS-IW

Device Description:

Centricity PACS-IW is an internet based software picture archiving and communications system that provides users with capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images (including digital mammograms).

Centricity PACS-IW includes features to access and manage medical imaging studies and data from computed tomography (CT), magnetic resonance (MR), ultrasound (US), nuclear medicine (NM), computerized radiography (CR), digital radiography (DR), digital mammography (MG), digital x-ray (DX), special procedures and Interventional radiography (XA), PET/CT scan (PT), and other imaging modalities.

Centricity PACS-IW is designed to be deployed over conventional TCP/IP networking infrastructure available in most healthcare organizations utilizing commercially available computer hardware platforms and operating systems. The system does not produce any original medical images. All images located in the Centricity PACS-IW have been received from DICOM compliant modalities and/or systems.

Intended Use:

Centricity PACS-IW by GE Healthcare is a device that receives medical images (including mammograms) and data from various imaging sources. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA-approved monitor that offers at least five Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Typical users of this system are trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians, and assistants.

Technology: The Centricity PACS-IW device employs the same fundamental scientific technology as its predicate device, Centricity PACS-IW cleared under K082318, with the following modifications:

- Upgrade of the Windows server and database management systems; and
- Support for JPEG lossless and JPEG non-wavelet compression techniques

Centricity PACS-IW receives medical images and other information from various data sources. The information can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations, the same as its predicate devices. Centricity PACS-IW is a software-only device that runs on commercially available off-the-shelf computer hardware platforms.

The Centricity PACS-IW device will continue to have an intended use and functionality fitting within the definition of 21 CFR 892.2050, Picture Archiving and Communication Systems, Product Code LLZ.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests

The software documentation was provided at a moderate level of concern following the FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Centricity PACS-IW complies with voluntary standards as detailed in this premarket notification submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Usability Analysis
- Testing on unit level (Verification)
- Integration testing (Verification)
- Performance testing (Verification)
- Regression testing (Verification)
- System testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket notification submission, Centricity PACS-IW, did not require clinical studies to support substantial equivalence.

Conclusion: Comparison of the Intended Uses, the technological characteristics, and performance specifications demonstrate the functional equivalence of the subject device to the predicate device. Verification and Validation testing results demonstrate that no adverse effects have been introduced by these differences.

Information provided in this premarket notification submission supports the Centricity PACS-IW medical device to be as safe, as effective and substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUN - 5 2012

Mr. John Manarik
Regulatory Affairs MAnager
GE Healthcare, HCIT
540 W. Northwest Highway
BARRINGTON IL 60010

Re: K121387
Trade/Device Name: Centricity* PACS-IW
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 4, 2012
Received: May 8, 2012

Dear Mr. Manarik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K121387

Device Name: Centricity* PACS-IW

Indications for Use:

Centricity PACS-IW by GE Healthcare is a device that receives medical images (including mammograms) and data from various imaging sources. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations.

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Prescription Use Yes AND/OR Over-The-Counter Use No
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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